Bard Electrophysiology
C.R. Bard, Inc.
55 Technology Drive
Lowell, MA 01851
(978) 441-6202
BardEP@CRBARD.COM
www.BardEP.com

7203 '00 JAN 14 A9:54

BARD

January 13, 2000

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services, rm. 1061
5630 Fishers Lane
Rockville, MD 20857

RE: Proposal to Docket Number 99P-4108/CP 1
Bard Temporary Pacing Electrode Catheters
Citizen Petition - Electrode Lead Wires and Patient Cables

Dear Ms. Jensen,

Thank you for taking the time today to discuss the above-mentioned Citizen Petition with myself and Gary O'Boyle, Bard EPs R & D Manager.

In your e:mail yesterday, you stated that Bard's petition is on hold pending some additional information regarding the development of adapters that will be compatible. Therefore, obviating the need for the variance. As we discussed earlier today, Bard has continued to pursue a solution in order to comply with the mandate, *Performance Standard for Electrode Lead Wires and Patient Cables.*

It is Bard's opinion that the proposed solution offered by Remington Medical, Inc. is not universal for all currently marketed External Pulse Generators (EPGs). The design of the Remington Medical cable will only interface with a Medtronic EPG due to the plug type connector on the proximal end of the cable, as the Medtronic EPG is the only device on the market that will accept the plug type connector. In addition, the plug connector, that is required to interface with the Medtronic pulse generator, is proprietary to Medtronic, and therefore not available to other catheter and cable manufacturers.

The only universal access to the currently marketed pulse generators is an exposed pin. This is the case when the Medtronic generator is used without a cable (as preferred by many users) or when a cable is not available. When a cable is not used, or is not available, the only access to the Medtronic generators is through additional ports on the generator which only accept an exposed pin. These additional ports are routinely used in emergency, life threatening situations when rapid pacing capability is required and/or no cable is available.

In order for the Bard Temporary Pacing Electrodes (TPEs) to have the ability to interface with all currently marketed EPGs, Bard believes that the only universal solution is to allow the use of a universal adapter. (See Fig.1)

99P-4108

Bard electrophysiology

SUP2

January 13, 2000

Proposal to Docket Number 99P-4108/CP 1
Bard Temporary Pacing Electrode Catheters
Citizen Petition - Electrode Lead Wires and Patient Cables

Bard's proposal for their TPEs is to convert to a protected pin configuration, thus complying with the standard. And, in order to interface with all currently marketed EPGs, Bard is proposing to package their TPEs (protected pin design) with, but not attached to the device, two (2) universal adapters.

Bard believes that this solution will allow the use of the protected pins for EPGs that may possibly accept them (although Bard does not believe that these are currently available), or to interface with a cable, such as that proposed by Remington Medical. Until such time that all manufacturers of EPGs are required to design their devices to accept protected pins, the use of universal adapters, as proposed here, is considered by Bard to be the only practical solution.

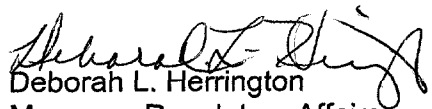
This becomes particularly important, and in Bard's opinion, imperative with respect to patient safety in situations when emergency pacing capability is required.

Please discuss the information contained in this letter and Bard's proposal with the appropriate individuals.

If you have any questions about this letter, please contact me at:

Bard Electrophysiology Division of C.R. Bard, Inc.
55 Technology Drive
Lowell, MA 01851
Telephone No.: 978-323-2216 (Direct Line)
Fax No.: 978-323-2222
e-mail: deborahherrington@crbard.com

Sincerely,



Deborah L. Herrington
Manager, Regulatory Affairs
Bard Electrophysiology

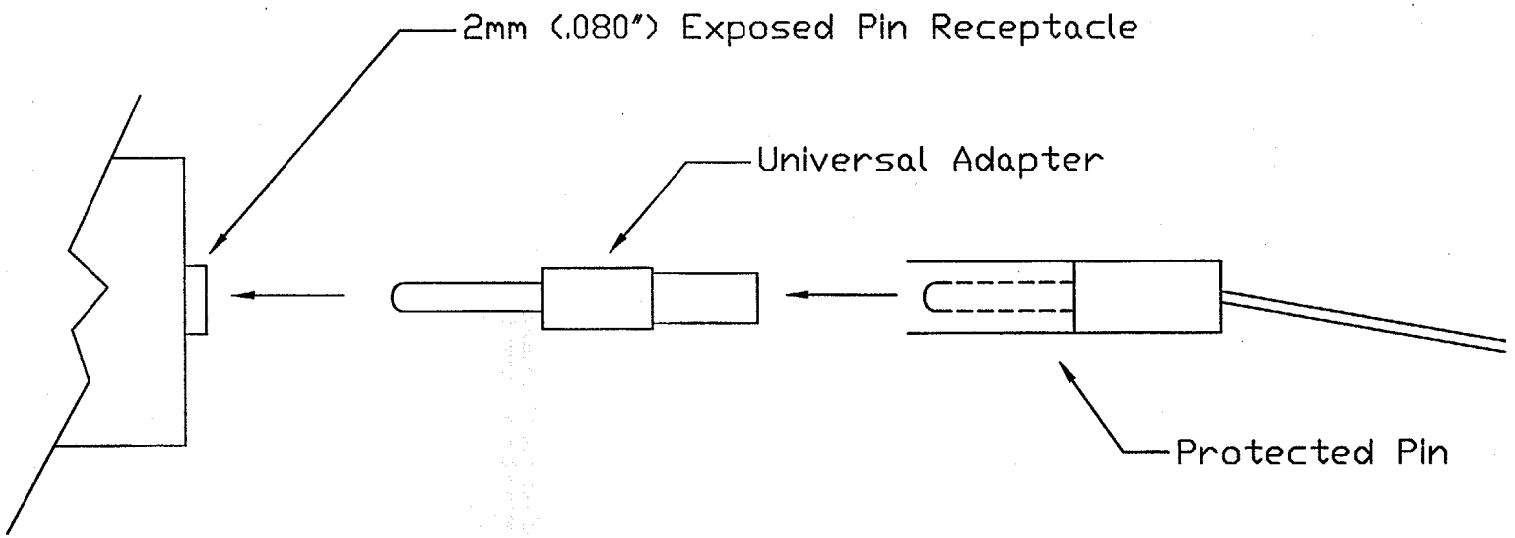

2mm (.080") Exposed Pin Receptacle
Universal Adapter
Protected Pin

Figure 1

Federal Express

P1

Bard
electrophysiology

Bard Electrophysiology
C.R. Bard, Inc.
129 Concord Road
Billerica, MA 01821

BARD

Dockets Management Branch
Food and Drug Administration
Dept of Health & Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20857

47-8990
x2216

Align top of FedEx PowerShip Label here

DAVE HEMENWAY
BARD ELECTROPHYSIOLOGY GROUP
55 TECHNOLOGY DRIVE
LOWELL MA 01851
(978)441-6202

SHIP DATE: 13JAN00
ACC # 136104861

ACTUAL WGT: 1 LBS SCALE

SEE ADDRESS LABEL ON PACKAGE FOR
THIS SHIPMENT TO MD 20857

FedEx.

4119 4515 1539

REF: 47-8990/D.HERRINGTON

PRIORITY OVERNIGHT F

cad # 0015070 13JAN00

Deliver
14JA

TRK# 4119 4515 1539 FORM 0201

IAD

20857 -MD-US ZMEDGA

The World On Time